

Notice of Allowability	Application No.	Applicant(s)	
	10/577,426	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Hai Vo	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed 09/14/2009.
2. ☒ The allowed claim(s) is/are 1,4, 7,8 and 15-17.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20091109</u> . 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Adaku Nwachukwu on 11/09/2009.

The application has been amended as follows:

The claims:

1. (Currently amended) A porous calcium phosphate ceramic body comprising a substrate having fine pores, and three-dimensional nanotunnel layers having pluralities of three-dimensionally connected nanotunnels formed on wall surfaces of said fine pores by mixing together calcium phosphate particles, a dispersant and water to form a slurry in a single dispersion state or near a single dispersion state, immersing said substrate in said slurry, and defoaming said slurry under reduced pressure, wherein said three-dimensional nanotunnel layers are formed in the fine pores inside the substrate, wherein a thickness of said three-dimensional nanotunnel layers is from 20 to 300 nm, wherein at least part of said nanotunnels have openings communicating with the fine pores of said substrate and said openings have an average diameter of 1 to 200 nm, and wherein the substrate and the three-dimensional nanotunnel layers are made from calcium phosphate.

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8. (Currently Amended) The porous calcium phosphate ceramic body according to claim 1, wherein ~~the~~ an atomic ratio of Ca/P in said three-dimensional nanotunnel layers is substantially equal to or smaller than that in said substrate.

17. (Currently Amended) A porous calcium phosphate ceramic body comprising a substrate having fine pores, and three-dimensional nanotunnel layers having pluralities of three-dimensionally connected nanotunnels formed on wall surfaces of said fine pores, wherein the three-dimensional nanotunnel layers are produced by a method comprising:

mixing together calcium phosphate particles, a dispersant and water to form a slurry in a single dispersion state or near a single dispersion state;

immersing the substrate in the slurry;

defoaming the slurry under reduced pressure;

drying the porous calcium phosphate ceramic body at a temperature below a boiling point of water, followed by a heat treatment at a temperature between 600 to 900°C;

wherein the three-dimensional nanotunnel layers are formed in the fine pores inside the substrate;

a thickness of said three-dimensional nanotunnel layers is from 20 to 300 nm;

at least part of said nanotunnels have openings communicating with the fine pores of said substrate and said openings have an average diameter of 1 to 200 nm;

the three-dimensional nanotunnel layers are from on 5 to 70% of the wall surface of said fine pores;

a mass ratio of the three-dimensional nanotunnel layers to the ceramic body is from 0.001 to 0.05; and

the substrate and three-dimensional nanotunnel layers are made from calcium phosphate.

Cancel claims 2, 5, 6, 9-12 and 14.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Note that the examiner's amendment is sufficient to overcome the art rejections and sufficient to place the instant claims in condition for allowance. Support for the amendment can be found at the description on pages 5 and 6, paragraphs 23 and 24; page 14, paragraph 56.

Of the references of record, the most pertinent are JP 03-065579 and Troczynski et al. (US 6,426,114).

JP '579 teaches an implantable article comprising a porous ceramic substrate and a ceramic coating formed in the fine pores inside the substrate. The ceramic coating is porous, having pores with an average pore size ranging from 200 to 500 nm and a thickness of 2 microns. This is way above the thickness from 20 to 300 nm set out in the claim range. Further, the porous ceramic coating is formed by applying a slurry onto the ceramic substrate and calcining the coated substrate. JP'579 uses a different process for making a porous ceramic body, there is no basis for establishing that the ceramic coating with three-dimensional nanotunnel layers that comprise pluralities of three-dimensionally connected nanotunnels would be inherently formed on the wall surfaces of the pores of the substrate. Finally, there is no motivation, no incentive to modify the implantable article of JP '579 to achieve the claimed invention.

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Troczyński discloses an implantable article comprising a porous substrate and a ceramic coating formed in the fine pores inside the substrate (example, column 7, lines 1-8). The porous substrate has pores with an average pore size of 50 to 200 microns and a porosity of 35 to 40% (column 7, lines 5-8). The porous coating is made from calcium phosphate coating which allows circulation of the physiological fluid throughout the coating structure (column 5, lines 33-36). This at least indicates that the ceramic coating is a three-dimensional structure having pores which are interconnecting with themselves so as to allow circulation of the physiological fluid throughout the coating structure. The coating material is uniform within the fine pores of the substrate (column 7, lines 5-10). Likewise, the coating is formed on 100% of the wall surface of the fine pores. The pores of the coating material are connected, ranging from 0.3 to 1 micron or 300 to 1000 nm (column 6, lines 55-60). The coating has the pores with an average pore size which is way above the claimed range, namely from 1 to 200 nm. Troczyński discloses that the novel process according to the reference can make a uniform bioceramic coating with a thickness ranging 1 to 5 microns while the widely used plasma spraying results in the bioceramic coating with a thickness from 10 to 100 microns (column 7, lines 53-60). Therefore, Troczyński fails to teach or suggest the coating having a thickness ranging from 20 to 300 nm. Note that Troczyński does not use the same approach for making a porous calcium phosphate ceramic body as presently claimed. Differences in process will result in the products which are not structurally identical. Accordingly, Troczyński does not contemplate the coating having the pores with an average pore size ranging from 1 to 200 nm and a coating thickness

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in the range from 20 to 300 nm. There is no motivation, no incentive to modify the porous ceramic body of Troczynski to achieve the claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794